**ATTORNEY'S DOCKET NUMBER: 2002941-0051**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Applicant: | Bachovchin *et al.* | Examiner: | Lukton, D. |
| Serial No.: | 08/950,542 | Art Unit: | 1653 |
| Filed: | October 15, 1997 | | |
| For: | INHIBITORS OF DIPEPTIDYL-AMINOPEPTIDASE TYPE IV | | |

**DECLARATION UNDER 37 C.F.R. 1.132**

I, Robert R. Rando, declare as follows:

1. I am a scientific consultant to Point Therapeutics, Inc., a licensee of the above-identified patent application, in the field of boroproline-containing peptides. I make this Declaration in support of an Amendment that has been filed in connection with the above-identified patent application.

2. I am a Professor in the Department of Biological Chemistry and Molecular Pharmacology at Harvard Medical School, Boston, MA. I have published extensively in the area of chemistry and biology of vision and signal transduction. Throughout my career, I have authored numerous peer reviewed articles and have made technical presentations at professional meetings in this field. I have extensive experience in enzyme characterization and am familiar with methods such as high performance liquid chromatograph (HPLC), enzyme activity assays, and chemical synthesis. A copy of my curriculum vitae, including a list of my publications, is attached hereto as EXHIBIT A.

3. Prior to making this declaration, I studied the following documents:

- U.S. Patent Application Serial No. 08/950,542, entitled, "Inhibitors of Dipeptidyl-Aminopeptidase Type IV", including a list of the claims pending as of May 14, 2002;
- W. Bachovchin, et al., J. Biol. Chem. 265:3738 (1990) ("Bachovchin JBC"); and
- W. Bachovchin Declaration (dated April 1, 1999).

4. I understand that the invention claimed in the above-identified patent application is directed to compositions containing a mixture of boroproline-containing peptides, in which at least 96% of the carbon atoms bearing the boron are of the L-configuration.

5. I have made certain observations and conclusions, which are stated below, based upon my study of the above-identified documents, my general academic training and my technical expertise.

6. I have reviewed the Bachovchin JBC reference and the Bachovchin Declaration and have concluded that the Bachovchin JBC does not disclose the purification of a boroproline-containing L-isomer. The Bachovchin Declaration includes an explanation as to why Dr. Bachovchin's original presumption that he had purified the L-isomer was incorrect and provides experimental evidence to support this explanation. (See Bachovchin Declaration, paragraphs 5-18). Accordingly, I have concluded that the Bachovchin JBC reference does not disclose the purification of an L-isomer of a boroproline-containing peptide using silica gel chromatography or any other method.

7. I have reviewed the above-identified patent application and, in particular, I have reviewed the descriptions of the purification methods appearing on pages 15 and 21 of the application. I have concluded that the description of the invention in the application is sufficient to allow a chemist of ordinary skill to make and use the claimed boroproline-containing L isomers for the following reasons.

8. The descriptions on pages 15 and 21 of the application disclose methods for purifying a boroproline-containing L isomer; however, the description on page 21 is unambiguous in its teachings that the HPLC C18 method can be used for this purpose, whereas the description on page 15 is equivocal. In particular, the page 15 description states (emphasis added):

> "The two diastereomers of Ala-boroPro-pinacol, L-Ala-D-boroPro-pinacol and L-Ala-L-boroPro-pinacol, can be partially separated by silica gel chromatography with 20% methanol in ethyl acetate as eluant. The early fraction *appears* by NMR analysis to be 95% enriched in one isomer. Because this fraction has more [sic] inhibits DP-IV to a greater extent than later fractions (at equal concentrations) it is *probably* enriched in the L-boroPro (L-Ala-L-boroPro-pinacol) isomer."

The use of equivocal language such as "appears" and "probably" suggests to me that the page 15 procedure is not the definitive procedure for purifying the L isomer of a boroproline-containing peptide. In contrast, the description on page 21 of the application unambiguously states that HPLC C18 chromatograph can be used to separate the L from D isomers:

> "High pressure liquid chromatography (HPLC) can be used to separate L-Pro-D-boroPro from L-Pro-L-boroPro. ... NMR and mass spectra analysis were consistent with both compounds being Pro-boroPro. Rechromatography of the purified isomers indicated that the first pass on the HPLC column achieved an isomeric purity of about 99-6% for each isomer. High pressure liquid chromatography (HPLC) can similarly be used ... to seperate [sic] the L-Ala-D-boroPro from L-Ala-L-boroPro or to seperate [sic] the D-boroPro from of other inhibitors from the L-boroPro form."

In view of these descriptions, I have concluded that there remained uncertainties regarding the utility of conventional silica gel chromatography described on page 15 for separating the L and D isomers but that the HPLC method described on page 21 of the application would be useful for this purpose.

9. As noted in the previous paragraph, page 21 of the application states, "the HPLC column achieved an isomeric purity of about 99-6% for each isomer". Although it is conventional to place the lower value number first in giving a range, the expression "99-6%" is consistent with an interpretation that the phrase "99-6%" refers to a range of about 96% to 99%. This interpretation also is consistent with a later publication by W. Gutheil and W. Bachovchin, "Separation of L-Pro-DL-boroPro into Its Component Diastereomers and Kinetic Analysis of Their Inhibition of Dipeptidyl Peptidase IV: A New Method for the Analysis of Slow, Tight-binding Inhibitors," Biochemistry 32:8723 (1993). This paper describes the separation of the L and D diastereomers by C18 HPLC and reports that a "purity of >98% for the purified products was indicated by analytical HPLC" (page 8727, right column, paragraph following Figure 3 legend). An interpretation that the phrase, "99-6%" refers to a range is consistent with the report of a purity >98% in Dr. Bachovchin's later publication of the separation process. The above-identified patent application contains various typographical errors; however even with these errors, the description of the invention would be understood by a practicing scientist.

10. It is my understanding that the U.S. Patent and Trademark Office has taken the position that one skilled in the art would have been motivated to purify the boroproline containing L-

greater potency. While it is true that the L-isomer might be expected to possess greater potency than the D-isomer, it must be remembered that the boroproline-containing peptides are designed for therapeutic use. This intended use is described on page 22 of the application. One skilled in the art would expect the D-isomers to have a longer half-life in vivo. In view of the intended therapeutic use of these compounds, it is my opinion that one skilled in the art would be motivated to isolate the D-isomers because of their greater half-life in vivo even if the D-isomers had a reduced potency compared to the L-isomers.

11. It also is my understanding that the U.S. Patent and Trademark Office has taken the position that one skilled in the art would have been motivated to use HPLC C18 chromatography to purify the boroproline-containing L isomers at the time the invention was made and also would have had a reasonable expectation that this method would be useful for achieving purification of the L isomer. I disagree with this conclusion for the following reasons. Although HPLC C18 columns were in general use at the time the priority application was filed (October 1991), a variety of purification techniques, such as HPLC using fine bore silica, chromatography using chiral matrix materials to separate stereoisomers, HPLC using other types of resins such as C8 columns, ion-exchange chromatography, and thin layer chromatography also were available. Even if one skilled in the art had been motivated to try one of these methods to separate the L and D isomers at the time the invention was made, it would not have been possible to know in advance which method would be useful for this purpose. Although one could have tried a variety of methods to separate the L and D isomers, the selection of a useful method would have required experimental testing.

12. I, the undersigned, declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this document and any patent which may issue from the above-identified patent application.

Dated: 5/21/02

Robert R. Rando

# CURRICULUM VITAE

Robert Richard Rando

Date of Birth: March 4, 1941

Place of Birth: New York, New York

Residence: 60 Montvale Road, Newton Centre, MA 02159
(617) 965-5798

Office: Department of Biological Chemistry and Molecular Pharmacology, Harvard Medical School,
240 Longwood Avenue, Boston, MA 02115

Telephone: (617) 432-1794; Fax: (617) 432-0471

Email: rando@hms.harvard.edu

## EDUCATION:

1962 B.S., Chemistry, Rutgers University, New Brunswick, NJ
1966 Ph.D., Physical-Organic Chemistry, Yale University, New Haven, CT
1981 A.M. (Hon.) Harvard University, Cambridge, MA

## POSTDOCTORAL:

1966-68 Research Associate, Department of Chemistry, Harvard University, Cambridge, MA

## APPOINTMENTS:

1968-72 Assistant Professor of Chemistry, Washington Square College of Arts and Sciences and the Graduate School of Arts and Sciences of New York University, NY

1972-75 Assistant Professor of Pharmacology, Harvard Medical School, Boston, MA

1974-90 Tutor in the Biochemical Sciences, Harvard University, Cambridge, MA

1975-80 Associate Professor of Pharmacology, Harvard Medical School, Boston, MA

[illegible] Professor of Pharmacology, Harvard Medical School, Boston, MA

1983-87 Gustavus Adolphus Pfeiffer Professor of Pharmacology, Harvard Medical School, Boston, MA

| | |
|---|---|
| 1987- | Professor of Biological Chemistry and Molecular Pharmacology, Harvard Medical School, Boston, MA |
| 1987- | Gustavus Adolphus Pfeiffer Professor of Biological Chemistry and Molecular Pharmacology, Harvard Medical School, Boston, MA |

FELLOWSHIPS AND AWARDS:

| | |
|---|---|
| 1963 | National Science Foundation Predoctoral Fellowship |
| 1963-66 | U.S. Public Health Service Predoctoral Fellowship |
| 1966-68 | U.S. Public Health Service Postdoctoral Fellowship |
| 1975-80 | U.S. Public Health Service Research Career Development Award |
| 1990-99 | U.S. Public Health Service MERIT Award |
| 1991 | Alcon Research Institute Award in Vision Research |

MEMBERSHIPS:

| | |
|---|---|
| 1963- | American Chemical Society |
| 1972- | American Association for the Advancement of Science |
| 1973- | American Society for Pharmacology and Experimental Therapeutics |
| 1980- | Association for Research in Vision and Ophthalmology |
| 1996 | American Academy of Arts and Sciences |

CURRENT EDITORIAL, GRANT REVIEW, AND FOUNDATION BOARDS:

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|---|---|
| 1989- | RP Foundation Fighting Blindness (Member of Scientific Advisory Board |
| 1991- | Alcon Research Institute (Member) |
| 1994- | Chemistry & Biology (Editorial Board) |
| 1997- | NIH Visual Sciences C Study Section (Member) |
| 1999 | Research to Prevent Blindness (Member of Scientific Advisory Board |

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